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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/068,215 | 02/06/2002 | Clive Wood | GNN-004BDV | 8509 |
| 959 | 7590 | 09/29/2005 | EXAMINER | |
| LAHIVE & COCKFIELD, LLP. 28 STATE STREET BOSTON, MA 02109 | | | OUSPENSKI, ILIA I | |
| | | | ART UNIT | PAPER NUMBER |
| | | | 1644 | |
| DATE MAILED: 09/29/2005 | | | | |

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/068,215

Applicant(s)

WOOD ET AL.

Examiner

ILIA OUSPENSKI

Art Unit

1644

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 13 July 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,4,9,10,29 and 30 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,4,9,10,29 and 30 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 7/13/2005.

- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

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DETAILED ACTION

1. Applicant's amendment/remarks, filed 07/13/2005, are acknowledged.

Claims 7 – 8, 11 – 15 and 19 – 22 have been cancelled.

Claims 2 – 3, 5 – 6, 16 – 18, and 23 – 28 have been cancelled previously.

Claim 1 has been amended.

Claims 29 – 30 have been added.

Claims 1, 4, 9 – 10, and 29 – 30 are pending.

2. This Office Action will be in response to applicant's arguments, filed 07/13/2005.

The rejections of record can be found in the previous Office Action, mailed 01/13/2005.

The text of those sections of Title 35 USC not included in this Action can be found in a prior Office Action.

It is noted that New Grounds of Rejection are set forth herein.

3. Applicant's IDS, filed 07/13/2005, is acknowledged, and has been considered.

Applicant has provided dates for references B7 – B10 in remarks filed 07/13/2005. However, these dates appear to be inconsistent with the dates cited on the respective documents, which dates have been filled in on the IDS.

4. The objections and rejections of record have been withdrawn in view of Applicant's amendment and arguments, except as set forth supra.

Art Unit: 1644

5. Claims 1, 4, and 9 – 10 stand rejected, and newly added claims 29 and 30 are rejected, under **35 U.S.C. 112, first paragraph**, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to practice the claimed method as it applies to the broad genus of “immune cell,” because it is unpredictable which “immune cells” express B7-4 and thus may be used in the claimed methods.

Applicant’s arguments have been fully considered but have not been found convincing.

Applicant argues that the specification provides extensive teaching regarding particular immune cells that Express B7-4, and points to examples of such teachings.

This is not found persuasive, because first, the examples encompass only a subset of immune cells, and second, all the examples provided by Applicant appear to be limited cells activated by specific stimuli. Therefore, the identity of the cells suitable for use in the instantly claimed methods, as well as the nature of pre-treatment these cells should receive to become useful, remain unpredictable, beyond the specific examples cited in the instant specification.

Applicant further argues that it would be no more than routine experimentation for one of skill in the art to determine the expression pattern of B7-4 by various types of immune cells.

Art Unit: 1644

This is not found persuasive, because although the methods of measuring expression levels of specific proteins are routine, the complexity of the immune system, and the large number of different types and subtypes of immune cells makes such experimentation unnecessarily, and improperly, extensive and undue.

Applicant is invited to consider amending the claims to limit the scope e.g. to specific cell types. Alternatively, Applicant is invited to consider amending the claims to recite "a method for upmodulating an immune response comprising administering an agent that downmodulates signaling ...", provided that the specification as filed provides adequate support under 35 USC 112, first paragraph, for such recitation. Applicant is reminded that any amendment must point to a basis in the specification so as not to add new matter. See MPEP 714.02 and 2163.06.

6. The following is a quotation of the second paragraph of 35 U.S.C. 112.

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

7. Claims 29 and 30 are rejected under **35 U.S.C. 112, second paragraph**, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 29 and 30 are indefinite in the recitation of "wherein the immune cells is ... a keratinocyte," because the recitation of "keratinocyte" lacks antecedent basis in the base recitation of an "immune cell," since keratinocytes are not considered in the art to be immune cells.

Therefore, one of ordinary skill in the art would not be reasonably apprised of the metes and bounds of the claimed invention.

Art Unit: 1644

Applicant is invited to consider re-writing the claim reciting "keratinocyte" in an independent claim format.

Applicant is reminded that any amendment must point to a basis in the specification so as not to add new matter. See MPEP 714.02 and 2163.06.

8. Conclusion: no claim is allowed.

The claims appear to be free of prior art.

9. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, THIS ACTION IS MADE FINAL. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to ILIA OUSPENSKI whose telephone number is 571-272-2920. The examiner can normally be reached on Monday-Friday 9 - 5.

Art Unit: 1644

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on 571-272-0841. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

ILIA OUSPENSKI

Patent Examiner

Art Unit 1644

September 23, 2005

Phillip Gambel

PHILLIP GAMBEL, PH.D

PRIMARY EXAMINER

TECH CAN 1600

9/23/05